

## **Frequently Asked Questions**

### Addressing Concerns Regarding Food Fortification

The Food Safety and Standards (Fortification of Foods) Regulations, 2018 have been notified in the Gazette of India on 2<sup>nd</sup> August 2018 which replace the standards operationalised earlier. The new standards now provide a minimum and a maximum range for fortification of staples like wheat flour (atta), maida, rice (with Iron, Folic Acid and Vitamin B12), double fortified salt (with Iodine and Iron), vegetable oil and milk (with Vitamin A and Vitamin D); the dosage of the micronutrients has been adjusted so that they provide 30 to 50 percent of the daily requirements. In Wheat Flour and Rice fortification, bioavailable sources of Iron have been added. Further, Vanaspati fortification has been excluded.

#### **1) Is food fortification mandatory or voluntary?**

There seems to be some confusion on whether fortification is mandatory. It is clarified that fortification continues to be voluntary. However, if any staple claims to be fortified, the standards as notified have to be followed. The intent is to ensure that the interest of the consumer is protected and the +F logo can only be used if the staple is fortified as per the regulations.

#### **2) What is Food Fortification and why do we need it?**

Food Fortification is a scientifically proven, cost-effective, scalable and sustainable global intervention that addresses the issue of micronutrient deficiencies. Nutrition is on the centre stage of the National Development Agenda with respect to Global Sustainable Development Goals (SDGs), with a clear focus on reduction of maternal, infant and young child mortality.

As per National Family Health Survey-4 (2015-16)<sup>1</sup>, public health concerns like Iron deficiency Anaemia is still prevalent in over 50 per cent of women (15- 45 years) and children under 5 years of age. As per the selected state-wide surveys conducted by the National Nutrition Monitoring Bureau (NNMB) of National Institute of Nutrition (NIN), Govt. of India, almost 62% of Indian population has low serum blood levels of vitamin A and 50%-94% of people in different states across India, suffer from vitamin D deficiency. Adverse functional outcomes like stunting, increased susceptibility to infectious diseases, physical impairments, cognitive losses, blindness and premature mortality are caused because of micronutrient deficiency.

#### **3) Is food fortification a scientifically proven intervention strategy?**

As per years of scientific evidence, fortification is a proven strategy to address micronutrient deficiencies. Studies conducted globally and in India show improved health conditions after fortification interventions.

A systematic review<sup>2</sup> of 201 studies was undertaken to assess the relevance and outcomes of food fortification. The review showed significant impacts on increased serum micronutrient concentrations of vitamin A and iron, when various population groups consumed foods that were fortified with vitamin A, iron and multiple micronutrients.

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<sup>1</sup>[http://rchiips.org/NFHS/factsheet\\_NFHS-4.shtml](http://rchiips.org/NFHS/factsheet_NFHS-4.shtml) (2015-16)

<sup>2</sup> Micronutrient fortification of food and its impact on woman and child health: a systematic review;

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3765883/>

Multiple studies have been conducted in India, keeping in mind the prevalence and environmental conditions, with significant sample size to assess the fortification as an intervention. The results show improved haemoglobin concentration, improved iron stores, better immunity, lowered incidence of diarrhoea and improved cognitive performance in children and other individuals.

#### **4) Global and Indian evidence on Food Fortification**

Across the globe, food fortification has been used safely and effectively to prevent vitamin and mineral deficiencies for more than a century. In 2008, the Copenhagen Consensus, a panel of Nobel laureates determined that providing micronutrients in the form of Iodized Salt, Vitamin A capsules and iron fortified flour for 80% of the world's malnourished would cost USD 347 million a year. This investment would yield USD 5 billion from avoided deaths, improved earnings and reduced health care spending. Numerous scientific studies conducted to examine the effect of consumption of fortified foods on Indian population have shown positive impact on health of the people. The impact has been in terms of improved immunity, plasma vitamin B-12 level, improving iron status, increase in haemoglobin concentrations, reducing the prevalence of anaemia (iron deficiency anaemia) and enhancing the cognitive performance in Indian children.

As per WHO guidelines<sup>7</sup>, food fortification has a proven history of use in countries globally for successful control of micronutrient deficiencies. Salt iodization was introduced in the early 1920s in both Switzerland and the United States of America and has since expanded progressively all over the world to the extent that iodized salt is now used in most countries. From the early 1940s onwards, the fortification of cereal products with thiamine, riboflavin and niacin became common practice. Margarine was fortified with vitamin A in Denmark and milk with vitamin D in the United States. Foods for young children were fortified with iron, a practice which has substantially reduced the risk of iron-deficiency anaemia in this age group. In more recent years, folic acid fortification of wheat has become widespread in the Americas, a strategy adopted by Canada and the United States and about 20 Latin American countries.

Food Fortification: Global Mapping Study 2016 by WHO<sup>3</sup>, has showcased positive consequences of fortification in many countries. Countries like Indonesia, Costa Rica, Côte d'Ivoire have shown successful results of oil fortification, iron fortification respectively. In Venezuela, wheat and maize flours have been fortified with iron, Vitamin A since 1993 and it has shown significant reduction in iron deficiency. In Morocco, fortification of double fortified salt showed improved results in reduction of anaemia<sup>4</sup>.

#### **5) Is fortification new to India?**

Food fortification is not a new idea in India. Fortification of Vanaspati, was mandated in 1953 and iodization of salt was mandated in 1962. India's 9<sup>th</sup><sup>5</sup> (National Nutrition Policy) 11<sup>th</sup><sup>6</sup> and 12<sup>th</sup> Plan<sup>7</sup> documents recommend fortification of staples with micronutrients. In order to achieve targeted outcomes over the next five years (2022), envisioned by the

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<sup>3</sup> [https://ec.europa.eu/europeaid/food-fortification-global-mapping-study-2016\\_en](https://ec.europa.eu/europeaid/food-fortification-global-mapping-study-2016_en)

<sup>4</sup> Guidelines on food fortification with micronutrients, WHO & FAO, 2006

<sup>5</sup> <http://planningcommission.nic.in/plans/planrel/fiveyr/welcome.html>

<sup>6</sup> [http://planningcommission.nic.in/plans/planrel/fiveyr/11th/11\\_v2/11th\\_vol2.pdf](http://planningcommission.nic.in/plans/planrel/fiveyr/11th/11_v2/11th_vol2.pdf)

<sup>7</sup> [http://planningcommission.nic.in/plans/planrel/fiveyr/12th/pdf/12fyp\\_vol3.pdf](http://planningcommission.nic.in/plans/planrel/fiveyr/12th/pdf/12fyp_vol3.pdf)

National Nutrition Strategy<sup>8</sup> on “Kuposhan Mukh Bharat”, food fortification has been identified as one of the strategies for implementation.

### **6) How is the micronutrient status of Indian population assessed?**

The data on micronutrient deficiencies is derived from Govt. of India’s National Surveys (RSOC / NFHS-4, 2015-16), and from the surveys / studies conducted by the most eminent scientists of the prestigious National Institute of Nutrition (NIN), under the aegis of Indian Council of Medical Research (ICMR), Govt. of India.

### **7) Is Food Fortification a replacement to dietary deficiency?**

Food fortification is a “complementary strategy<sup>9</sup>”, and “not a replacement of balanced, diversified diets” to address malnutrition. Dietary diversification is indeed the best choice but in the current scenario it may be difficult to achieve by everyone, therefore a more universal approach is needed to address the issue. Dietary diversification, supplementation and food fortification are not “Either / Or” choices but “Complementary strategies”. Fortification only bridges the gap between the need and actual consumption of required micronutrients through food.

As per the 68<sup>th</sup> Round of Household Consumer Expenditure Survey<sup>10</sup> across Socio-economic Groups, conducted by NSSO, Government of India, 2011-12, the consumption levels of fruits and vegetable, as well as of meat, fish and eggs are very low which are the best sources of micronutrients. People in India consume large amounts of cereals (about 300g/day), Fair amount of oil (about 25g/day) and milk (about 170 g/day), and very low intake of other foods such as vegetables, fruits and eggs / meat and fish. Consumption of vegetables other than potatoes is about 50g/day and of fruits is about 30g/day. The average weekly consumption of eggs is about 2 eggs per person and of meat is about 70g. The National Nutrition Monitoring Bureau (NNMB), and the latest Rapid Survey on Children (RSOC) reveal that the intake of foods rich in micronutrients is far less than the recommended intakes.

As per the selected state-wide surveys conducted by the National Nutrition Monitoring Bureau (NNMB) of National Institute of Nutrition (NIN), Govt. of India:

- a. Over 86% of Indian population is not consuming enough vitamin A-rich foods. Hence, almost 62% of Indian population has low serum blood levels of vitamin A; and
- b. about 50%-94% of people in different states across India, suffer from vitamin D deficiency

### **8) How was the consensus built for regulations on food fortification?**

On 16<sup>th</sup> October 2016, National Summit on Food fortification was held announcing the operationalising the standards of fortification. The operationalised standards were kept open for public comments. In 2017, five national consultations, five zonal consultations, various industry consultations (Oil (3), Salt (3), Milk (3), Wheat flour (4), rice (1)) and 11 state level meetings were held to take the consensus of the national stakeholders before putting the efforts on scaling-up of food fortification. After various deliberations and comments received from the stakeholders, the Scientific Panel comprising of eminent scientists from academia and premier research institutes of the country recommended the

<sup>8</sup> [http://niti.gov.in/writereaddata/files/document\\_publication/Nutrition\\_Strategy\\_Booklet.pdf](http://niti.gov.in/writereaddata/files/document_publication/Nutrition_Strategy_Booklet.pdf)

<sup>9</sup> Guidelines on food fortification with micronutrients, WHO & FAO, 2006

<sup>10</sup> [http://mospi.nic.in/sites/default/files/publication\\_reports/nss\\_report\\_560\\_19dec14.pdf](http://mospi.nic.in/sites/default/files/publication_reports/nss_report_560_19dec14.pdf)

final standards (with minimum and maximum levels) for fortified foods which have been notified on 2<sup>nd</sup> August 2018 as Food Safety and Standards (Fortification of Foods) Regulations, 2018.

**9) Thalassaemic patients or people on low iron diets should not consume foods fortified with iron. How has FSSAI addressed this concern?**

Food Safety and Standards (Fortification of Foods) Regulations, 2018 distinctly mentions that the package (label) of food fortified with Iron i.e Wheat Flour, Maida, Rice and Double Fortified Salt shall carry a mandatory declaration: *“People with Thalassaemia may take under medical supervision”*.

**10) Will regular intake of Fortified staples cause any adverse effects if entire meal is fortified?**

The dosages added to the staples are adjusted to provide only 30-50 percent of an individuals’ daily nutrient requirement. To take care of any concerns, the standards of fortification have been developed based on detailed analysis of consumption pattern, RDA requirements, dietary diversification, and compliance to supplementation intake. Less than 0.02% of nutritional premix is added as a fortificant, which is well below the Tolerable Upper Limit as per FAO/WHO guidelines. These standards have been developed by the Scientific Panel on Fortification and Nutrition which include eminent public health experts from premier academic and medical institutes such as AIIMS, ICMR, NDRI, Nutrition foundation of India along with representations from government like Ministry of Women and Child Development, etc.

**11) How will food fortification impact if supplementation is also taken?**

Food fortification helps build body stores over time, whereas micronutrient supplementation is a short-term strategy of giving a large dose of the micronutrient as a medicinal supplement. It has been effective in providing immediate relief in several countries. But the status of micronutrient supplementation in India is poor.

(i) As per Rapid Survey of Children, conducted by MWCD, GOI, in 2013-14:

- a. Only 45% children aged 6-59 months received vitamin A supplementation in six months preceding the survey.
- b. Only 13 percent of the children aged 6-59 months received IFA supplementation in 6 months preceding the survey.
- c. Only 29 percent of the women from the urban and 21 percent of the women from the rural areas consumed the requisite quantity (100 or more) IFA tablet/syrup, during pregnancy.

(ii) NFHS-4 2015-16 data shows that:

- a. Just about 30% of women consumed IFA supplements and
- b. About 60% children below 5 years had atleast 1 dose of vitamin A

**12) How can fortification reach regional areas and benefit population groups that live in the interiors of the country?**

As per NFHS-4, the Indian population is found micronutrient deficient. Fortification targets the entire population and thus, ensuring continuous supply of fortified foods in open

market is needed as fortification is voluntary. The fortified staples provide only 30-50 percent of daily value of the RDA, and the dosage has been set keeping in mind that the diet pattern of the population may include diversification and supplementation.

Ministry of Women and Child Development and Department of School Education and Literacy have issued directives for mandatory use of fortified staples (Wheat Flour, Oil and DFS) in ICDS and MDM, respectively in 2017. The implementation of these directives will ensure that the nutritional benefit of fortification reaches the masses, especially the vulnerable segments of society.

To promote large scale food fortification as a supplementary strategy to address micronutrient deficiencies, the Food Fortification Resource Centre (FFRC) has been set up in FSSAI with the support of TATA Trusts. The FFRC works with various government partners and development agencies to assist in implementation of directives issued by MWCD and MHRD. Statements of Disclosure from TATA Trusts, GAIN and PATH are annexed.

**13) Is fortification driven primarily by commercial interests and will it adversely impact the national economy?**

In the backdrop of the data as above, it can be seen that the current drive on fortification addresses a critical public health concern. With such high levels of micronutrient malnutrition, food fortification offers a very cost-effective solution as a supplementary intervention. Fortification technology is easy and indigenous and does not require huge investments. No specialised equipment is required for the fortification process. The equipment required for fortification in most of the cases are already available with the manufacturers.

The basic raw material (premixes of vitamins and minerals), used for fortification is produced both in the country and imported. As the demand of the fortified staples will increase, it will also encourage the building of indigenous capacities and create business opportunities for the local manufacturers. This will ensure that even at the block level fortified staples will be available and also provide livelihoods to the medium and small enterprises.

**14) How does fortification address the sentiments of vegetarian people?**

The fortificants that are used are of PLANT ORIGIN, and hence good for all, without conflicting with religious / cultural beliefs of people. In particular, for Vitamin D, the Food Safety and Standards (Fortification of Foods) Regulations, 2018, clearly mentions the source of nutrient as “**only from plant source**”.

**15) Are the vitamins and minerals added to the food natural or synthetic in nature?**

Micronutrients are produced in plants and animals through enzymatic processes. The industrial production of synthetic micronutrients is carried out through microbial fermentation, or chemical synthesis, followed by extraction.

Many fruits and vegetables are good sources of vitamins, like oranges for vitamin C. On the other hand, animal products like milk, meat and fish are better sources of vitamins A, D, E, B12 etc. One would think that natural vitamins are superior to synthetic because it relates

to fresh fruits, vegetables and food. Comparative bioavailability studies in humans have also shown very small and insignificant differences between synthetic and natural vitamin C, regardless of the subject population, study design or intervention used.

For using vitamins from dietary sources, besides their availability and affordability, there are issues related to adjusting potency or dosage, their bioavailability, and food sensitivities of the population. However, irrespective of the source, whether natural or synthetic, the molecular structure and activity or potency of a vitamin is identical.

#### **16) How is food fortification cost-effective?**

The incremental cost of food fortification is minimal (Rs. 0.02/ litre of milk, Rs. 0.10/ Kg of wheat flour and Rs. 0.10/ Kg of edible oil). By incurring these minimal costs, the disease burden of widely prevalent problems like anaemia can be reduced. It is a well-established fact that micronutrient malnutrition can impose significant costs on economic development in terms of reduced labour productivity, increased healthcare costs and overall growth and development of the nation.

As per Copenhagen Consensus (2008), one rupee spent on fortification will yield nine rupees' benefits to the economy.

### **Annexure**

#### **Statement of Disclosure**

##### **TATA Trusts**

*“Tata Trusts are amongst India's oldest, non-sectarian philanthropic organisations. The Trusts own two-third of the stock holding of Tata Sons, the apex company of the Tata group of companies. The wealth that accrues from this asset supports an assortment of causes, institutions and individuals in a wide variety of areas. In this manner, the profits that the Tata companies earn go back many times over to the communities they operate in. These funds have been deployed towards a whole range of community development programmes across the country, for over a 100 years now.*

*Since its inception, Tata Trusts have played a pioneering role in transforming traditional ideas of charity and introducing the concept of philanthropy to make a real difference to communities. Through grant-making, direct implementation and co-partnership strategies, the Trusts support and drive innovation in the areas of healthcare and nutrition; water and sanitation; energy; education; rural livelihoods; natural resource management; urban poverty alleviation; enhancing civil society and governance; media, arts, crafts and culture; and diversified employment. The Trusts engage with competent individuals and government bodies and like-minded NGO's to nurture a self-sustaining eco-system that collectively works across all these areas. “*

##### **Program for Appropriate Technology in Health (PATH)**

*“PATH is a 40-year-old non-profit organization working to accelerate health equity, so all people and communities can thrive. PATH has been working in the area of nutrition in India for more than two decades to address the challenges of malnutrition. Addressing malnutrition requires a holistic approach that involves dietary diversification, fortification, supplementation and public health measures. All these approaches should not be seen in isolation but rather as complementary strategy to address the problem of malnutrition in India.*

*PATH does not believe in promoting the agenda of private sector players and our action have demonstrated our resolve to work for the betterment of base of the pyramid population. PATH does not believe in promoting the agenda of private sector players and our action have demonstrated our resolve to work for the betterment of base of the pyramid population. PATH works multi-sectoral with Government, academia, research organizations and local institutions and develop sustainable approaches, promote indigenous solutions and build local capacity to address the problem of health and malnutrition.”*

### **Global Alliance for Improved Nutrition (GAIN)**

*“GAIN does not have a conflict of interest whatsoever in promoting fortification of staple foods to address micronutrient deficiencies amongst the population and particularly poor and vulnerable sections. Staple Food Fortification is a proven complementary strategy to preventing malnutrition globally and adopted by multiple countries. GAIN believes that staple food fortification contributes to reduction in micronutrient deficiencies but is not a substitute for a diversified nutritious hygienic diet.*

*Globally, GAIN works to promote the consumption of safe and nutritious foods for all people everywhere, and particularly the most vulnerable. We are a non-profit foundation headquartered in Geneva, and do not promote the commercial interests of specific food industry players. We work in alliances to ensure the broadest consultations and cooperation amongst governments, private sector, civil society and the scientific community to ensure safe and nutritious food is more available, desirable and affordable for all and particularly the poor. This principle is reflected in our work globally and in India.”*